

|   |  |   |
|---|--|---|
| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>   |  | <b>ATTORNEY'S DOCKET NUMBER</b><br>M/43212-US-1<br><br><b>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)</b><br>10/539,505 |
| <b>INTERNATIONAL APPLICATION NO.</b><br>PCT/EP03/14331  | <b>INTERNATIONAL FILING DATE</b><br>12/16/2003 | <b>PRIORITY DATE CLAIMED</b><br>12/17/2002  |
| <b>TITLE OF INVENTION</b><br>Formulation Comprising Fenofibric Acid, A Physiologically Acceptable Salt or Derivative Thereof  |  |   |
| <b>APPLICANT(S) FOR DO/EO/US</b><br>Jorg ROSENBERG  |  |   |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:   |  |   |
| 1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.<br>2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.<br>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).<br>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.<br>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).<br>a. <input type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).<br>Items 11 to 20 below concern document(s) or information included:<br>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.<br>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.<br>13. <input type="checkbox"/> A preliminary amendment.<br>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.<br>15. <input type="checkbox"/> A substitute specification.<br>16. <input type="checkbox"/> A power of attorney and/or change of address letter.<br>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.<br>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). |  |   |

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

|   |              |   |         |                          |              |
|---|--------------|---|---------|--------------------------|--------------|
| U.S. APPLICATION NO. (if known, see 37 CFR 1.5)   |              | INTERNATIONAL APPLICATION NO.   |         | ATTORNEY'S DOCKET NUMBER |              |
| 10/539,505  |              | PCT/EP03/14331  |         | M/43212-US-1             |              |
| 20. Other items or information:   |              |   |         |                          |              |
| The following fees have been submitted  |              |   |         | CALCULATIONS             | PTO USE ONLY |
| 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))..... \$300  |              |   |         | \$                       |              |
| 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))  |              |   |         | \$                       |              |
| If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0   |              |   |         |                          |              |
| All other situations..... \$200   |              |   |         |                          |              |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))   |              |   |         | \$                       |              |
| If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... \$0  |              |   |         |                          |              |
| Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100  |              |   |         |                          |              |
| International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... \$400   |              |   |         |                          |              |
| All other situations..... \$500   |              |   |         |                          |              |
| TOTAL OF 21, 22 and 23 =  |              |   |         |                          |              |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).<br>The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |              |   |         |                          |              |
| Total Sheets  | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE    |                          |              |
| - 100 =   | /50 =        |   | x \$250 | \$                       |              |
| Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).   |              |   |         | \$ 130.00                |              |
| CLAIMS  | NUMBER FILED | NUMBER EXTRA  | RATE    | \$                       |              |
| Total claims  | - 20 =       |   | x \$ 50 | \$                       |              |
| Independent claims  | - 3 =        |   | x \$200 | \$                       |              |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |              |   | + \$350 | \$                       |              |
| TOTAL OF ABOVE CALCULATIONS =   |              |   |         | \$                       |              |
| <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.  |              |   |         |                          |              |
| SUBTOTAL =  |              |   |         | \$                       |              |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).   |              |   |         | \$                       |              |
| TOTAL NATIONAL FEE =  |              |   |         | \$                       |              |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property  |              |   |         | \$ 40.00                 |              |
| TOTAL FEES ENCLOSED =   |              |   |         | \$ 170.00                |              |
|   |              |   |         | Amount to be refunded:   | \$           |
|   |              |   |         | Amount to be charged     | \$           |

01/11/2006 ATRAH1 00000051 10539505

01 FC:1617

130.00 OP

BEST AVAILABLE COPY

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-1437. A duplicate copy of this sheet is enclosed.
- d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

NOVAK DRUCE DELUCA & QUIGG, LLP  
1300 I STREET, N.W., 400 EAST TOWER  
WASHINGTON, DC 20005



SIGNATURE

S. Peter Konzal

NAME

53,152

REGISTRATION NUMBER

1/9/2006

BEST AVAILABLE COPY

**BEST AVAILABLE COPY**

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

Due: 1/10/2006

|                             |                       |                  |
|-----------------------------|-----------------------|------------------|
| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
| 10/539,505                  | Jorg Rosenberg        | M/43212-US-1     |

26474  
 NOVAK DRUCE DELUCA & QUIGG, LLP  
 1300 EYE STREET NW  
 SUITE 400 EAST  
 WASHINGTON, DC 20005

|                               |               |
|-------------------------------|---------------|
| INTERNATIONAL APPLICATION NO. |               |
| PCT/EP03/14331                |               |
| I.A. FILING DATE              | PRIORITY DATE |
| 12/16/2003                    | 12/17/2002    |

CONFIRMATION NO. 4705  
 371 FORMALITIES LETTER



\*OC000000017431643\*

Date Mailed: 11/10/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 06/17/2005
- Copy of the International Search Report filed on 06/17/2005
- Copy of IPE Report filed on 06/17/2005
- Preliminary Amendments filed on 06/17/2005
- Request for Immediate Examination filed on 06/17/2005
- U.S. Basic National Fees filed on 06/17/2005
- Priority Documents filed on 06/17/2005

NOVAK DRUCE - DC  
 DOCKETED  
 DATE: 11/10/05  
 BY: [Signature]

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$130** for a Large Entity:

- **\$130** Surcharge.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

SHAKEEL AHMED

Telephone: (703) 308-9140 EXT 208

PART 1 - ATTORNEY/APPLICANT COPY

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/539,505                  | PCT/EP03/14331                | M/43212-US-1     |